

The Cataract National Dataset electronic multi-centre audit of 55 567 operations: risk indicators for monocular visual acuity outcomes

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Abstract

Aims To report risk factors for visual acuity (VA) improvement and harm following cataract surgery using electronically collected multi-centre data conforming to the Cataract National Dataset (CND).

Methods Routinely collected anonymised data were remotely extracted from the electronic patient record systems of 12 participating NHS Trusts undertaking cataract surgery. Following data checks and cleaning, analyses were performed to identify risk indicators for: (1) a good acuity outcome (VA 6/12 or better), (2) the pre- to postoperative change in VA, and (3) VA loss (doubling or worse of the visual angle).

Results In all, 406 surgeons from 12 NHS Trusts submitted data on 55 567 cataract operations. Preoperative VA was known for 55 528 (99.9%) and postoperative VA outcome for 40 758 (73.3%) operations. Important adverse preoperative risk indicators found in at least 2 of the 3 analyses included older age (3), short axial length (3), any ocular comorbidity (3), age-related macular degeneration (2), diabetic retinopathy (3), amblyopia (2), corneal pathology (2), previous vitrectomy (2), and posterior capsule rupture (PCR) during surgery (3). PCR was the only potentially modifiable adverse risk indicator and was powerfully associated with VA loss (OR = 5.74).

Conclusion Routinely collected electronic data conforming to the CND provide sufficient detail for identification and quantification of preoperative risk indicators for VA outcomes of cataract surgery. The majority of risk

indicators are intrinsic to the patient or their eye, with a notable exception being PCR during surgery.

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Introduction

Monocular visual acuity (VA) is widely used as an outcome measure following cataract surgery despite its known limitations.¹ The near universality of its use and the relative ease with which it can be collected mean that this practice is likely to continue in the foreseeable future, at least until a validated and well-accepted alternative is developed. Routine collection of clinical data using electronic patient records has made it possible to undertake multi-centre audit and analysis of significant numbers of cataract surgical procedures through extraction and aggregation of detailed and standardised clinical records data. In the current report from our collaborative series,^{2–8} we provide information on risk indicators for VA outcomes of cataract surgical procedures.

Materials and methods

The method of extraction and aggregation of multi-centre data has previously been reported.⁶ Extracted data included pre-, intra-, and postoperative data.

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VA data were recorded in one or more of three ways at each clinical encounter. These were uncorrected, corrected (habitual or best correction), and using a 'pinhole' correction. As before, we have pragmatically designated the term 'best-measured VA' preoperatively as the better VA either corrected (habitual/best correction) or uncorrected (UCVA); where no result was available for either of these two measures, pinhole VA was resorted to as a proxy. In contrast, postoperatively the 'best-measured VA' was the best VA obtained from any one of: the corrected VA (usually best-corrected VA (BCVA), ie, optimal postoperative refraction), the UCVA, or the pinhole VA.⁶ In some contributing centres postoperative VA data were collected before postoperative refraction, which necessitated the inclusion of pinhole correction on such occasions.

Three multivariable risk factor analyses were undertaken with the STATA statistical software package to examine different aspects of monocular VA outcomes. Logistic regression was used to assess candidate indicators for a good VA outcome (6/12 or better), multiple regressions for pre- to postoperative change in VA, and logistic regression for the analysis of risk indicators for clinically significant visual loss following surgery (doubling or worse of visual angle pre- to postoperatively). Snellen acuities were converted to LogMAR acuity for analyses; all analyses included adjustment for preoperative baseline VA (as a continuous variable) and adjustment for paired eyes to acknowledge within-patient inter-eye correlation. The following terms were included in each model: age, sex, any ocular comorbidity, age-related macular degeneration, glaucoma, diabetic retinopathy, brunescant/white cataract, high myopia, corneal pathology, amblyopia, uveitis/synechiae, no fundal view/vitreous opacities, pseudoexfoliation/phacodonesis, previous vitrectomy, previous retinal detachment surgery, axial length (quintiles), pupil size, inability to co-operate, unable to lie flat, any alpha blocker, tamsulosin, doxazosin, alfuzosin, indoramin, prazosin, terrazosin, surgeon grade, and posterior capsule rupture (PCR) during surgery. Stepwise forward and backward fitting was used for each of the models, which were restricted to main effects as the number of potential interaction terms would have been unmanageable. The final models were assessed for fit using the C-Stat or area under the receiver-operator characteristics curve for logistic regressions and R^2 for multiple regression.

Results

In all, 406 surgeons from 12 NHS Trusts submitted data on 55 567 cataract operations between November 2001 and July 2006 (86% from January 2004). Preoperative

'best-measured' VA was known for 55 528 (99.9%) and postoperative 'best-measured' VA outcome for 40 758 (73.3%) operations (median follow-up 35 days). Optimal postoperative refracted VA or BCVA was available for 24 404 eyes (43.9%).

Good outcome: VA 6/12 or better

Postoperatively 37 096 (91.0%) eyes achieved 6/12 or better acuity. The results of the logistic regression for factors significant at the 5% level, adjusted for baseline VA, are presented in Table 1. Because of a large sample size and a relatively common outcome (91.0%) the statistical power of this model was high and for this reason caution should be exercised when interpreting small effects with limited statistical significance such as $0.67 < OR < 1.5$ and/or $0.05 < P < 0.01$ as these may be clinically unimportant. Table 1 shows that factors with $OR < 1$ were less likely and those with $OR > 1$ were more likely to be associated with a good VA outcome of 6/12 or better. Factors with $OR > 1.5$ associated with a good VA outcome included: brunescant/white cataract and no fundal view/vitreous opacities. Similarly, factors with $OR < 0.67$ associated with a less favourable VA outcome (worse than 6/12) included: older age, short axial length, any ocular comorbidity, age-related macular degeneration, diabetic retinopathy, amblyopia, corneal pathology, previous vitrectomy, the alpha blocker prazosin, and PCR during surgery.

Change in VA pre- to postoperatively

The results of the multiple regression analysis for change in VA from pre- to postoperative status are presented in Table 2, adjusted for baseline VA. The effect sizes (ESs) are formatted as LogMAR lines (five letters per line, eg, one line change equivalent Snellen 6/12 to 6/9+ or 6/30 to 6/24). The average change between preoperative VA (0.54 LogMAR, equivalent Snellen 6/21 approximate) and postoperative VA (0.14 LogMAR, equivalent Snellen 6/8 approximate) was 4.0 LogMAR lines or 20 LogMAR letters improvement. Factors with +ve values represent associations with greater than average improvement and factors with -ve values represent associations with worse than average improvement. This model was likewise highly statistically powered and again caution should be exercised in interpretation of small ES such as less than half a LogMAR line above or below average, that is, $\leq \pm 2$ LogMAR letters or 0.4 LogMAR lines difference (equivalent Snellen 6/12 to 6/13 approximate) and/or borderline statistical significance $0.05 < P < 0.01$ as these may be clinically unimportant. Based on these criteria it can be seen from Table 2 that the only factor with a non-trivial ES ($> +0.4$ LogMAR lines) associated

Table 1 Risk factors/indicators of a good VA outcome: post-operative VA 6/12 or better

Variable	Adjusted odds ratio (95% CI) ^a	P-value
Age		
<60	1.00	<0.0001
60–69	0.75 (0.61, 0.93)	
70–79	0.55 (0.46, 0.67)	
80–89	0.31 (0.26, 0.38)	
90+	0.17 (0.14, 0.22)	
Axial length^b		
≤22.37	0.65 (0.57, 0.73)	<0.0001
22.38–22.95	0.89 (0.79, 1.01)	
22.96–23.47	1.00	
23.48–24.18	1.08 (0.95, 1.23)	
≥24.19	1.01 (0.89, 1.16)	
Any ocular comorbidity		
No	1.00	
Yes	0.46 (0.41, 0.52)	<0.0001
Age-related macular degeneration		
No	1.00	<0.0001
Yes	0.57 (0.50, 0.65)	
Diabetic retinopathy		
No	1.00	<0.0001
Yes	0.41 (0.34, 0.49)	
Amblyopia		
No	1.00	<0.0001
Yes	0.38 (0.31, 0.48)	
Corneal pathology		
No	1.00	<0.0001
Yes	0.56 (0.45, 0.71)	
High myopia		
No	1.00	0.0156
Yes	0.74 (0.58, 0.94)	
Previous vitrectomy		
No	1.00	<0.0001
Yes	0.25 (0.17, 0.37)	
Previous retinal detachment surgery		
No	1.00	0.0376
Yes	0.67 (0.46, 0.98)	
Brunescent or white cataract		
No	1.00	<0.0001
Yes	2.16 (1.71, 2.72)	
No fundal view/vitreous opacities		
No	1.00	0.0008
Yes	1.76 (1.26, 2.44)	
Prazosin		
No	1.00	0.0010
Yes	0.29 (0.14, 0.61)	
Posterior capsule rupture		
No	1.00	<0.0001
Yes	0.41 (0.32, 0.53)	

Table 1 (Continued)

Variable	Adjusted odds ratio (95% CI) ^a	P-value
Surgeon grade		
Consultant	1.00	0.0360
Associate specialist	1.24 (1.07, 1.43)	
Staff grade	1.15 (0.86, 1.54)	
Fellow	1.05 (0.86, 1.26)	
Specialist registrar	1.06 (0.96, 1.16)	
SHO	0.92 (0.78, 1.08)	

Logistic regression analysis with adjustment for baseline VA; N = 40 646; C-Stat or area under ROC curve = 0.81.

^aThe odds ratio refers to the likelihood of achieving a good outcome of VA 6/12 or better. Factors with OR < 1 were less likely and those with OR > 1 were more likely to be associated with a good VA outcome.

^bAxial length divided into quintiles.

with better than average VA improvement was brunescent/white cataract, and the magnitude of this effect was only slightly more than half a line better than the average improvement. On the other hand there were many factors that were associated with more than two letters below average improvement (ES < -0.4 LogMAR lines): older age, short axial length, any ocular comorbidity, age-related macular degeneration, diabetic retinopathy, amblyopia, corneal pathology, previous vitrectomy, previous retinal detachment surgery, and PCR during surgery.

VA loss of ≥3 LogMAR lines of acuity

Clinically significant vision loss was defined as a doubling or worse of the visual angle (loss of 3 LogMAR lines) between pre- and postoperative assessments (eg, LogMAR 0.3 to 0.6 or equivalent Snellen 6/12 to 6/24). There were 507 (1.24%) eyes that experienced this level of loss of vision. The risk indicators for acuity loss are presented in Table 3, adjusted for baseline VA. In this table an OR < 1 indicates that the factor is protective against loss of vision and an OR > 1 indicates that the factor is associated with a higher risk of VA loss. Because the outcome of interest was relatively uncommon (1.24%) statistical power was less and there is less justification for a strict interpretation of small effects as clinically unimportant though the use of multiple testing should be borne in mind where 0.05 < P < 0.01. Significant factors associated with loss of vision were older age, short axial length, any ocular comorbidity, diabetic retinopathy, small pupil size, and PCR during surgery, the latter being the most powerful factor with an OR of 5.74.

Discussion

In these analyses of a large sample of routine NHS cataract operations we have focused on three related but

Table 2 Risk factors/indicators of the pre- to postoperative change in VA

Variable	Adjusted difference in means (95% CI) ^a	P-value
Age		
< 60	0.00	<0.0001
60–69	–0.29 (–0.40, –0.19)	
70–79	–0.75 (–0.85, –0.66)	
80–89	–1.33 (–1.43, –1.23)	
90 +	–2.18 (–2.37, –1.99)	
Gender		
Female	0.00	0.0003
Male	0.10 (0.04, 0.15)	
Axial length^b		
≤ 22.37	–0.47 (–0.55, –0.39)	<0.0001
22.38–22.95	–0.12 (–0.20, –0.05)	
22.96–23.47	0.00	
23.48–24.18	0.05 (–0.02, 0.12)	
≥ 24.19	–0.06 (–0.13, 0.02)	
Any ocular comorbidity		
No	0.00	<0.0001
Yes	–0.52 (–0.63, –0.42)	
Age-related macular degeneration		
No	0.00	<0.0001
Yes	–0.94 (–1.10, –0.78)	
Diabetic retinopathy		
No	0.00	<0.0001
Yes	–0.97 (–1.19, –0.75)	
Amblyopia		
No	0.00	<0.0001
Yes	–1.16 (–1.46, –0.87)	
Corneal pathology		
No	0.00	<0.0001
Yes	–0.69 (–0.95, –0.43)	
High myopia		
No	0.00	0.0372
Yes	–0.27 (–0.52, –0.02)	
Previous vitrectomy		
No	0.00	<0.0001
Yes	–2.14 (–2.74, –1.53)	
Previous retinal detachment surgery		
No	0.00	0.0169
Yes	–0.47 (–0.86, –0.08)	
Brunescent or white cataract		
No	0.00	0.0012
Yes	0.53 (0.21, 0.85)	
Pupil size at surgery		
Large	0.00	0.0136
Medium	0.07 (–0.01, 0.15)	
Small	–0.19 (–0.36, –0.02)	

Table 2 (Continued)

Variable	Adjusted difference in means (95% CI) ^a	P-value
Inability to cooperate		
No	0.00	0.0027
Yes	–0.25 (–0.41, –0.09)	
Tamsulosin		
No	0.00	0.0495
Yes	0.24 (0.01, 0.46)	
Posterior capsule rupture		
No	0.00	<0.0001
Yes	–1.12 (–1.47, –0.77)	

Multiple regression analysis; N = 40 625; R² for model = 0.69.

^aEffect size refers to LogMAR lines of change, eg, eyes with amblyopia experienced on average 1.16 LogMAR lines less improvement than those with no amblyopia after adjustment for baseline VA and other significant effects.

^bAxial length divided into quintiles.

slightly different aspects of postoperative monocular VA outcome: good VA (LogMAR ≤0.3, ie, Snellen 6/12 or better), change in VA pre- to postoperatively, and loss of VA with doubling or worse of the visual angle pre- to postoperatively. This approach has allowed different aspects of outcome to be highlighted separately with good VA outcome indicators for a favourable end result, change in VA probing indicators for the effectiveness of surgery to improve VA, and loss of VA probing indicators for acuity loss related to surgery. Not surprisingly, several of the significant risk factors found were common to all three analyses, though certain interesting differences also emerged.

In overview, the results appeared favourable, with analyses indicating substantial levels of VA benefit and low levels of harm. Thus, 91% of the eyes achieved a favourable outcome of 6/12 or better with an average VA improvement of 4.0 LogMAR lines (20 LogMAR letters; equivalent Snellen 6/21 to 6/8 approximate). A clinically significant loss of vision with doubling of the visual angle occurred in 1.24% of eyes, indicating that surgery was relatively safe, with perioperative damage to vision being reasonably uncommon.

The important adverse preoperative risk indicators found in at least two of the three analyses included older age (3), short axial length (3), any ocular comorbidity (3), age-related macular degeneration (2), diabetic retinopathy (3), amblyopia (2), corneal pathology (2), previous vitrectomy (2), and PCR during surgery (3). All these preoperative adverse risk indicators are outside of the surgeon's control. Appropriate actions, however, would include ensuring that the patient is correctly informed of a guarded prognosis, and, where surgical difficulty is anticipated (eg, corneal pathology or previous vitrectomy), that the operation is undertaken by

Table 3 Risk factors/indicators of clinically significant loss of vision: doubling or worse of pre- to postoperative visual angle, eg, 6/12 to 6/24

Variable	Adjusted odds ratio (95% CI) ^a	P-value
<i>Age</i>		
<60	1.00	0.0026
60–69	0.87 (0.54, 1.39)	
70–79	1.08 (0.72, 1.63)	
80–89	1.36 (0.91, 2.05)	
90+	1.93 (1.14, 3.29)	
<i>Axial length^b</i>		
≤22.37	1.51 (1.16, 1.96)	<0.0001
22.38–22.95	0.99 (0.74, 1.31)	
22.96–23.47	1.00	
23.48–24.18	0.97 (0.72, 1.29)	
≥24.19	0.77 (0.56, 1.05)	
<i>Any ocular comorbidity</i>		
No	1.00	<0.0001
Yes	2.28 (1.87, 2.77)	
<i>Diabetic retinopathy</i>		
No	1.00	0.0078
Yes	1.73 (1.16, 2.59)	
<i>Pupil size at surgery</i>		
Large	1.00	0.0012
Medium	0.78 (0.57, 1.08)	
Small	1.85 (1.26, 2.70)	
<i>Posterior capsule rupture</i>		
No	1.00	<0.0001
Yes	5.74 (3.93, 8.40)	

Logistic regression analysis with adjustment for baseline VA; N = 40,678; C-Stat or area under ROC curve = 0.71.

^aThe odds ratio refers to the risk of a doubling or worse of the visual angle between pre- and postoperative measurements, eg, eyes in which a posterior capsule rupture has arisen intraoperatively are 5.74 times more likely to suffer a doubling or worse of the visual angle compared with those without this intraoperative complication.

^bAxial length divided into quintiles.

a suitably experienced surgeon. When interpreting our results it should be born in mind that all the specific comorbidities listed were also included within the ‘Any Ocular Comorbidity’ category. Within the statistical models a small proportion of the effect from the itemised comorbidities may have contributed to the ES of ‘Any Ocular Comorbidity’, but there were also a range of less common comorbidities, included in ‘Other’, which individually were not important but when grouped together formed a significant group.

PCR deserves special consideration and this complication has long been regarded as a benchmark for the quality of cataract surgery. In all three of our analyses, this operative event was found to be highly statistically significant. Associated with this event was a 59% reduction (OR = 0.41) in the likelihood of achieving

a good outcome (6/12 or better); eyes on average had 1.12 LogMAR or just over one line (5.6 LogMAR letters) less improvement in vision, and there was a 5.74 times increased likelihood of eyes with PCR suffering loss of vision to the extent of a doubling or worse of the visual angle. These results underline the importance of avoiding PCR whenever possible by adopting strategies to minimise this risk for patients whose predicted probability of a capsule rupture is elevated. Our previous work has drawn attention to the preoperative factors associated with capsule rupture and the importance of ensuring that appropriately skilled surgeons undertake higher-risk operations.^{2,5} The most experienced and highly skilled surgeons are not only best placed to anticipate and head off intraoperative difficulties as surgical events unfold, but in the event of a complication they are also best placed to deal with an adverse surgical situation in a way that minimises, as far as possible, resulting harm.

Unexpectedly, ‘brunescent or white cataract’, and less consistently ‘no fundal view/vitreous opacities’, appeared to be associated with enhanced VA benefit from surgery. In the absence of other explanations it is possible that this observation may have arisen as a result of inaccurate adjustment for baseline acuity. Many of these eyes are likely to have had very poor preoperative VA and at the extreme end of the scale our method of LogMAR VA extrapolation may well have been inaccurate and produced a spurious result (ie, CF, HM, and PL scored as LogMAR 2.1, 2.4, and 2.7, respectively). Alternatively, these cases may have been handled by the most highly skilled surgeons who were able to make the most of a difficult surgical challenge. However, the first logistic regression model included surgical grade, so this effect was accounted for in the analysis as presented, and in the other two models the effect of surgical grade was not found to be statistically significant.

Our findings are in keeping with a number of earlier studies. It is to be expected that poor preoperative VA would be associated with large improvements in VA following uneventful surgery; a ceiling effect on the VA scale means that there is less ‘room for improvement’ for eyes with relatively good preoperative VA. Each of our analyses was adjusted for preoperative VA to account for this expectation. Older age, ocular comorbidity and ‘surgical complexity’ have also previously been noted as being associated with a worse VA outcome.^{9–12}

One of the strengths of our study is the large sample size and the wealth of detailed preoperative data available for analysis. This can only be achieved through prospective routine electronic data collection, the analysis being a by-product of routine clinical care. This approach has allowed us to uncover a number of previously unidentified specific risk indicators for adverse monocular VA outcome following cataract

surgery. In our sample the completeness of the preoperative data was very high,^{5,6} but because of varying patterns of patient care in different centres we did not have the same levels of data completeness for postoperative VA outcome (73.3%), which we acknowledge as a relative weakness.

Conclusion

Our objective with this analysis was to examine predictors of monocular VA outcome from a number of different perspectives. In keeping with earlier studies, we have confirmed that older age, ocular comorbidity, and operative complications are associated with worse outcomes. To this we have added detailed information regarding the risks for specific types of ocular comorbidity. An important finding is the magnitude of the impact of capsule rupture on VA outcome, in particular its strong association with VA loss (OR = 5.74; <0.0001). This powerful finding underlines the relevance and importance of PCR as an accepted benchmark of surgical quality.

As an outcome, monocular VA does, however, have significant limitations, as it does not fully reflect the overall visual experience of the person who has undergone surgery. Patient-reported outcome measures will in future be needed to address postoperative outcome more fully.

Summary

What was known before

- Monocular visual acuity outcomes following cataract surgery vary according to preoperative acuity, ocular comorbidity, and 'surgical complexity'.

What this study adds

- Detailed risk factor analyses adjusted for baseline acuity on a large sample of cataract operations has quantified significant risk indicators for acuity outcome, including a range of specific ocular comorbidities, short axial length, and posterior capsule rupture during surgery. The only potentially avoidable risk factor for pre- to postoperative loss of vision was posterior capsule rupture during surgery with an odds ratio of 5.74.

Conflict of interest

RL Johnston is a Director of Medisoft Limited. The other authors declare no conflict of interest.

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defensible decision making algorithm for revalidation based on case mix adjusted measures of surgical performance', which was administered through the Royal College of Ophthalmologists.

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